FORM PTO-1390 (REV. 5-93)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTORNEY'S DOCKET NUMBER 2565/52
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371		U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 09/308914

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/EP98/01792	(26.03.98) 26 March 1998	(26.09.97) 26 September 1997

TITLE OF INVENTION
PUMPING AND METERING DEVICE

APPLICANT(S) FOR DO/EO/US
HERKLOTZ, Martin; SCHNEIDER, Hans-Peter; BIGALKE, Jörg; DÖNIG, Rainer; HÄCKER, Jürgen

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This express request to begin national examination procedures (35 U.S.C. 371(f)) immediately rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☐ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☒ has been transmitted by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US)
6. ☒ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ have been transmitted by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☒ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

tems 11. to 16. below concern other document(s) or information included:

1. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
2. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.

☒ A **FIRST** preliminary amendment.

☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.

☐ A substitute specification.

☐ A change of power of attorney and/or address letter.

☐ Other items or information: International Search Report, PCT/RO/101

U.S. APPLICATION NO. if known, see 37 C.F.R.1.5	INTERNATIONAL APPLICATION NO. PCT/EP98/01792	ATTORNEY'S DOCKET NUMBER 2565/52

17. ☐ The following fees are submitted:

Basic National Fee (37 CFR 1.492(a)(1)-(5)):
Search Report has been prepared by the EPO or JPO $840.00

International preliminary examination fee paid to USPTO (37 CFR 1.482) . $670.00

No international preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2)) $760.00

Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO $970.00

International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4) $96.00

	CALCULATIONS	PTO USE ONLY
ENTER APPROPRIATE BASIC FEE AMOUNT =	$840.00	
Surcharge of $130.00 for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(e)).	$	

Claims	Number Filed	Number Extra	Rate		
Total Claims	28 - 20 =	8	X $18.00	$144.00	
Independent Claims	4 - 3 =	1	X $78.00	$78.00	
Multiple dependent claim(s) (if applicable)			+ $260.00	$	
			TOTAL OF ABOVE CALCULATIONS =	$1062.00	
Reduction by ½ for filing by small entity, if applicable. Verified Small Entity statement must also be filed. (Note 37 CFR 1.9, 1.27, 1.28).				$	
			SUBTOTAL =	$1062.00	
Processing fee of $130.00 for furnishing the English translation later the ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(f)).			+	$	
			TOTAL NATIONAL FEE =	$1062.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). $40.00 per property			+	$	
			TOTAL FEES ENCLOSED =	$1062.00	
			Amount to be: refunded	$	
			charged	$	

a. ☐ A check in the amount of $_____ to cover the above fees is enclosed.

b. ☒ Please charge my Deposit Account No. 11-0600 in the amount of $1062.00 to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 11-0600. A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

Kenyon & Kenyon
One Broadway
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Richard L. Mayer
By: Mary C. Werner Reg No 31,333
SIGNATURE

Richard L. Mayer, Reg. No. 22,490
NAME

22,490 May 26, 1999
REGISTRATION NUMBER DATE

88789-1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Herklotz, Martin et al.

For: PUMPING AND METERING DEVICE

Serial No.: National Phase of PCT/EP98/01792

International Filing Date: March 26, 1998

Art Unit: To be determined

Examiner: To be determined

Assistant Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

SIR:

Prior to calculation of the filing fee of the above-referenced application, please cancel claims 2 through 19.

Respectfully submitted,

Dated: May 26, 1999

Thomas J. Meloro
Reg. No. 33,538

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88029-1

EL234416127US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Herklotz, Martin et al.
For:	PUMPING AND METERING DEVICE
Serial No.:	National Phase of PCT/EP98/01792
International Filing Date:	March 26, 1998
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Examiner:	To be determined

Assistant Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

SIR:

Prior to examination of the above-referenced application on the merits, please enter the following amendments:

In the Specification:

Please insert the following headings into the specification:

At page 1, line 1, "Field of the Invention;"

At page 1, line 18, "Background of the Invention;"

At page 2, line 17, "Objects of the Invention;"

At page 7, line 16, "Brief Description of the Figures;"

At page 7, line 24 Detailed Description of the Preferred Embodiment."

Please enter the following additional amendments:

At page 1, lines 10-11, "is that it combines the advantages of piston machines [can

be combined] with;"

At page 2, lines 12-13, "pulses, [due to] variable loads or [due to] inadequate;"

At page 3, line 24, "electromechanical, or [and/or] electric sensors;"

At page 4, lines 15-16, "delivery unit described herein [according to claim 1, for example], the membrane;"

At page 4, line 33, "membrane material for [of] the membrane unit;"

At page 5, lines 10-11, "necessary to clean relatively inaccessible [difficulty accessible] components;"

At page 5, lines 19-20, "the effect of preventing [that] impurities from entering [cannot enter] the dialysis fluid and [no] dialysis fluid from entering [can enter];"

At page 7, line 15, "drawings. [, which show];"

At page 8, lines 17-18, "piston 7[,] is designed as a precision piston, with the piston rod [runs] running in a precision cylinder;"

At page 8, lines 31-33, "by a computer, and it turns the device off when the pressure reaches [on reaching or exceeding] a definable limit valve;"

At page 8, line 33, "maximum pressure [head]."

In the Claims

Please cancel claims 1 through 19 and enter new claims 20 through 47.

20. A pumping device for delivering and metering medical fluids comprising:

a. a membrane unit having a membrane bordering a first chamber;

b. a pumping unit connected to the first chamber by a hydraulic unit containing hydraulic fluid that is in fluid connection with the first chamber;

c. a measuring device for measuring the pumping unit output; and

d. a control unit connected to the measuring device and the pumping unit; wherein the control unit is adapted and arranged for controlling the pumping unit output based on the measurements of the measuring device.

21. The device of claim 20, wherein the pumping unit output is selected from the group consisting of the metering rate and quantity of fluid.

22. The device of claim 20, wherein the pumping unit has a driving device and a piston.

23. The device of claim 22, wherein the piston includes a piston head and a piston shaft.

24. The device of claim 23, wherein the measuring device is adapted to measure the pumping unit output by determining the axial position of the piston.

25. The device of claim 20 where the measuring device includes sensors selected from the group consisting of optical, electromechanical and electrical sensors.

26. The device of claim 22, wherein the piston is arranged on a chassis.

27. The device of claim 20, wherein the membrane has a first and a second layer of a non-stretching material forming an interspace therebetween, the interspace being filled with a non-compressible medium such that the membranes have an outward bulge.

28. The device of claim 27, wherein the non-compressible medium is a spacer.

29. The device of claim 23, wherein the measuring device is adapted and arranged to determine the axial position of the piston shaft.

30. The device of claim 21, further comprising a computer connected to the measuring device and the control unit, wherein the computer is adapted for calculating parameters for the pumping device, wherein the parameters are selected from the group consisting of volume of fluid delivered, metering rate or delivery rate.

31. The device of claim 20, further comprising a hydraulic sensor in fluid connection with the hydraulic unit, the hydraulic sensor adapted and arranged for measuring the pressure of the fluid within the hydraulic unit.

32. The device of claim 31, wherein the control unit is connected to the hydraulic sensor and wherein the control unit is adapted for shutting off the pumping unit in response to a measured pressure outside a predetermined range.

33. The device of claim 22, wherein the driving device includes a linear drive.

34. The device of claim 33, wherein the linear drive is selected from the group consisting of eccentric drives, spindle drivers, rack and pinion drives, pneumatic pistons and compressor drives.

35. The device of claim 1 wherein the hydraulic unit includes a vent valve.

36. The device of claim 30 wherein the computer is integrated into the control unit.

37. A pumping device for delivering and metering medical fluids comprising:

a. a membrane having a first membrane bordering a first chamber;

b. a membrane pump head mounted on the membrane unit, the membrane pump head having a second membrane bordering a second chamber, the second chamber having an inlet and an outlet for conveying medical fluids and wherein the second membrane is in air-free contact with the first membrane;

c. a pumping unit connected to the first chamber by a hydraulic unit containing hydraulic fluid that is in fluid connection with the first chamber;

d. a measuring device for measuring the pumping unit output; and

e. a control unit connected to the measuring device and the pumping unit, the control unit being adapted and arranged for controlling the pumping unit

output based on the measurements of the measuring device;

wherein movement of fluid in the first chamber induces movement of fluid in the second chamber.

38. The device of claim 37, wherein the movement of fluid out of the first chamber induces the movement of fluid into the second chamber.

39. The device of claim 37, wherein the membrane pump head is detachably mounted on the membrane unit.

40. The device of claim 37, wherein closing means are provided for closing the inlet and outlet of the second chamber.

41. The device of claim 40, wherein the closing means are selected from the group consisting of clamps or valves.

42. The device of claim 37, further comprising a hydraulic sensor in fluid connection with the hydraulic unit, the hydraulic sensor adapted and arranged for measuring the pressure of the hydraulic fluid.

43. The device of claim 42, wherein the control unit is connected to the hydraulic sensor and wherein the control unit is adapted for shutting off the pumping unit in response to a measured pressure outside a predetermined range.

44. A pumping device for delivering and metering medical fluids comprising:

a. a membrane unit having a first membrane bordering a first chamber;

b. a membrane pump head mounted on the membrane unit, the membrane pump head having a second chamber bordered by the first membrane on the side opposite the first chamber, the second chamber having an inlet and an outlet for conveying medical fluids;

c. a pumping unit connected to the first chamber by a hydraulic unit

containing hydraulic fluid in fluid connection with the first chamber;

d. a measuring device for measuring pumping unit output; and

e. a control unit connected to the measuring device and the pumping unit, the control unit being adapted and arranged for controlling the pumping unit output based on the measurements of the measuring device;

wherein movement of fluid in the first chamber induces movement of fluid in the second chamber.

45. The device of claim 44, wherein the membrane pump head is detachably mounted on the membrane unit.

46. A method of pumping medical fluids comprising the steps of:

a. providing a fluid to be treated to a device comprising:

i. a membrane having a first membrane bordering a first chamber;

ii. a membrane pump head mounted on the membrane unit, the membrane pump head having a second membrane bordering a second chamber, the second chamber having an inlet and an outlet for conveying medical fluids and the second membrane is in air-free contact with the first membrane;

iii. a pumping unit connected to the first chamber by a hydraulic unit containing hydraulic fluid that is in fluid connection with the first chamber;

iv. a measuring device for measuring the pumping unit output; and

v. a control unit connected to the measuring device and the

pumping unit, the control unit being adapted and arranged for adjusting the pumping unit output based on the measurements of the measuring device;

wherein movement of fluid in the first chamber induces movement of fluid in the second chamber;

b. reducing the pressure on the hydraulic fluid in the hydraulic unit such that the fluid to be treated flows out of the first chamber, thereby causing fluid to flow into the second chamber through the fluid inlet;

c. applying pressure to the hydraulic fluid in the hydraulic unit via the pumping unit such that fluid is forced into the first chamber; wherein the movement of the first membrane forces fluid out of the second chamber through the fluid outlet;

d. measuring the pumping unit output and transmitting the measurement to the control unit; and

e. adjusting the pumping unit output.

47. The method of claim 46, wherein the pumping device further includes a computer connected to the control unit, the computer adapted and arranged for calculating pumping unit parameters selected from the group consisting of volume of fluid delivered, metering rate and delivery rate, and wherein the method further includes the step of calculating a pumping unit parameter.

REMARKS

Claims 20 through 47 are pending in the current application. The amendments are intended to clarify the Applicants' invention and correct informalities in the application.

Applicants believe that this application is in condition for allowance and respectfully request that such action be taken. If the Examiner believes that prosecution of this application would be advanced by contact with Applicants' attorney, the Examiner is invited to contact the undersigned at the telephone number given below.

Respectfully submitted,

Dated: May 26, 1999

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88097-1

Pumping And Metering Device

The present invention relates to a pumping device for delivering, balancing and metering fluids, in particular medical fluids such as blood or dialysis fluids, with a driving device and a piston unit including a piston and a membrane unit having a membrane and a first chamber bordered by the membrane. The pumping device also includes a hydraulic unit having a space to accommodate a hydraulic fluid which is connected to the piston of the piston unit and to the first chamber of the membrane unit.

An important advantage of such a pump system is that the advantages of piston machines can be combined with those of membrane units. The piston unit, which operates as a piston pump, serves as an internal displacement pump which is connected to the membrane of the membrane unit by a hydraulic fluid. The hydraulic fluid is in a closed system and transmits the axial movement of the piston to the membrane, which is moved accordingly in the membrane unit.

Precise metering of fluids is important, for example, in the area of dialysis, where fluids with a known composition must be conveyed at precisely definable rates. The dialysis fluids used here are composed of numerous substances, the type and quantity of which must be based on the needs of an adequate and individualized patient treatment. The essential functions of a dialysis machine include pumping the fluid at precisely predetermined metering rates and quantitative determination of the quantities pumped for the purposes of balancing. One disadvantage of the known dialysis systems is that these functions must be executed by different units, which results in heavy and complex machines that are difficult to handle.

A compact metering system is known, for example, from European Patent No. 376,497 from the field of coating semiconductor components, where precise delivery and metering of liquid media is also necessary. A generic pumping device is described here, where a membrane is in contact on one side

with a hydraulic fluid in a suitable space. The desired movement of the membrane is accomplished with a piston movement, with the movement of a piston of the piston unit being transmitted to the membrane by the hydraulic fluid. This metering unit is controlled on the basis of the number of pulses per unit of time which are applied to the motor driving the piston. The relationship between the number of pulses per unit of time and the desired delivery head of the pumping device is determined by calibration before use and is used to control the pumping device in operation. One disadvantage of such a procedure is that, for example, due to faulty determination of the required number of pulses, due to variable loads or due to inadequate calibration, there may be a faulty relationship between the number of pulses per unit of time and the delivery head, which makes accurate metering difficult.

The object of the present invention is to improve upon a pumping device in such a way as to increase the reliability of metering and balancing.

This object is achieved on the basis of a generic pumping device by providing a control unit for controlling a predefinable metering rate and/or quantity as well as a measuring device by means of which the axial position of the piston of the piston unit can be determined directly and which can be connected to the control unit. In this way, it is possible to determine the piston position directly and reliably and, after taking the time into account, the change over time can be determined, with the determination being independent of the functioning and reliability of the drive unit. In addition to these functions of metering and delivery, the device according to the present invention also fulfills the function that the quantity of fluids delivered can be quantified, thus permitting balancing, e.g., during a dialysis treatment. This creates a compact and reliable delivery, metering and balancing system that permits favorable manufacturing and maintenance in addition to offering space and weight advantages. In particular, the system according to

the present invention is suitable for hemodialysis, because a performance spectrum with small dimensions is created that makes superfluous the use of additional control and monitoring equipment which would necessitate the patient's stay in a clinic or hospital. Additional fields of application of the pumping device according to the present invention include peritoneal dialysis, hemofiltration and related methods. Owing to the directly determinable position of the piston and the piston speed which can be determined from that, the pumping device according to the present invention permits calculation of all necessary system data, such as the volume delivered or the delivery rate by taking into account the average area of the piston. In addition to the above-mentioned kinematic parameters, the pressure conditions can also be monitored and regulated due to the use of a hydraulic sensor. Moreover, partial volumes can also be detected and adjusted.

It is especially advantageous if the piston has a piston head for delivering the hydraulic fluid as well as a piston shaft and if the measuring device is arranged in such a way that the axial position of the piston shaft can be determined.

The measuring device according to the present invention with which the axial position of the piston and the piston shaft can be determined directly may have optical, electromechanical, and/or electric sensors.

According to a preferred embodiment, a second chamber can be formed by a membrane pump head detachably mounted on the membrane unit, with the second chamber being arranged on the membrane side opposite the first chamber and with the membrane pump head having at least one inlet and at least one outlet. The second chamber serves as a delivery chamber holding the medium to be delivered, while the first chamber is acted upon by hydraulic fluid to induce a corresponding movement of the membrane.

In the mounted state of the membrane pump head, the second chamber can be directly adjacent to the membrane of the membrane unit. In this case, the membrane is acted upon by fluid from both sides, with the hydraulic fluid being on one

side of the membrane and the fluid to be delivered being on the other side of the membrane.

It is especially advantageous if the second chamber is bordered by a membrane which is adjacent to the membrane of the membrane unit when the membrane pump head is in the mounted state. In this case, the two membranes are adjacent to one another, with the movement of the hydraulic fluid first inducing movement in the membrane of the membrane unit, and due to the contact of this membrane with the membrane of the head piece, the fluid to be delivered is introduced into the second chamber or removed from it accordingly. Such a design of the pumping device according to the present invention is advantageous in particular because in this case there are two completely separate systems. Although the pumping device according to the present invention is the delivery unit according to Claim 1, for example, the membrane pump head with the membrane serves to seal the medium to be pumped and to separate substances with the device according to the present invention. As a result of this separation of substances, neither the hydraulic fluid nor the medium to be pumped becomes contaminated, but also the parts of the pumping device according to the present invention are neither attacked nor contaminated by the medium to be pumped. In this case, the choice of membrane material of the membrane unit will not depend primarily on the corrosion properties but instead will depend primarily on the criterion of long-term stability.

In another embodiment of the present invention, the inlet and/or outlet of the head piece can be closed off. To that effect, valves or clamps in particular are provided. These have the function of causing the outlet of the head piece to be blocked when the medium to be pumped is being drawn into the second chamber, while the inlet valve is closed and the outlet valve is opened accordingly when the intake medium is being ejected. It is not necessary here for all the fluid in the second chamber to be delivered in the ejection operation. Instead, it is possible for only a quantity of intake fluid corresponding to the maximum possible piston position to be

ejected.

It is especially advantageous if the head piece is designed in such a way that it can be used for a single use. While the pumping device according to the present invention serves the function of accurately moving the membrane and thus metering, the head piece has the function of executing the actual delivery of fluid. The exchangeable head piece, which is designed as a disposable article according to the present embodiment and can be mounted on the pumping device, has the advantage that it is not necessary to clean difficultly accessible components such as valves, because the head piece is not reused after a single use. Thus, the membrane of the membrane unit forms the interface of the pumping device with the head piece designed as a disposable article in which the substance transport and delivery of media to and from the patient are to take place. The definite media separation, which prevents direct contact between the media to be pumped and machine system parts in the pumping device according to the present invention, has the effect that impurities cannot enter the dialysis fluid and no dialysis fluid can enter the pumping device due to leakage, for example. Another advantage is that the metering and balancing accuracy of the pumping device is independent of the dimensional accuracy of the head piece, which is designed as a disposable article, because all the components necessary for balancing and metering are provided in the piston pumping device and not in the mountable membrane pump head.

In another embodiment of the present invention, a pressure sensor is provided that is connected to the space of the hydraulic unit. By using such a pressure sensor in the hydraulic unit, an individually adjustable delivery pressure limit and display can be achieved for the system. This is important in particular when the outlet valve of the head piece inadvertently fails to open, for example.

It is especially advantageous if the pressure sensor can be connected to the drive of the piston unit. This makes it possible for the pressure sensor to interrupt pump operation

on reaching a limit value to limit the forces introduced into the system.

In another embodiment of the present invention, the driving device of the piston unit includes a linear drive. Examples of suitable linear drives include, for example, eccentric drives, spindle drives and rack and pinion drives as well as pneumatic pistons with compressor drives.

The hydraulic system of the pumping device according to the present invention may have a vent valve, which guarantees that the hydraulic fluid is free of gases. This is especially important because the movements of the piston unit and the membrane can be coordinated accurately only when the transmission medium is incompressible, as is the case with gas-free fluids, for example.

In another embodiment of the present invention, a computer unit is provided and is connected to the measuring device and/or the control unit and it can perform the balancing of the media pumped. Because of the direct determination of the piston position and the determination of the change over time, it is possible to determine the media pumped up to that point, which is necessary for accurate monitoring of the process.

The computer unit can be integrated into the control unit.

To improve handling of the pumping device according to the present invention, the piston unit may be arranged on a chassis.

It is especially advantageous if the membrane of the membrane unit has two membrane layers made of a non-stretching material and an interspace filled with an incompressible medium extending between the two membrane layers, so that the membrane layers have an outward bulge with respect to the interspace. Such a design prevents the disadvantage associated with the elastic membranes known in the past, when there is an unwanted deformation or deflection of the membrane due to the pressure difference between the two sides of the membrane. As a result of this deflection, an exact correlation between the

position of the piston of the piston unit and the membrane deflection and thus accurate metering are impossible unless the pressure conditions are always constant. On the other hand, the membrane according to the present invention is always kept in a definite position regardless of the pressure conditions, so that a reproducible correlation between piston movement and quantity delivered is guaranteed.

In another embodiment of the present invention, the membrane layers are arranged with a separation between them by a spacer. With a suitable design of the spacer, this facilitates filling of the interspace between the membrane layers in particular.

Additional details and advantages of the pumping device according to the present invention are apparent from the drawings, which show:

Figure 1: a schematic diagram of the pumping device according to the present invention;

Figure 2: a perspective view of the pumping device according to the present invention with the piston unit and the membrane unit; and

Figure 3: a sectional diagram through a pumping device according to the present invention with a membrane unit having a two-layer membrane.

As Figure 1 shows, a pump drive which includes a linear drive, for example, drives the piston of a unit which is shown here as a piston pump. The measurement device according to the present invention, which is shown as a path sensor in the embodiment according to Figure 1, determines the exact position of the piston.

Use of a piston pump as the metering unit is based on the fact that piston pumps are preferred for use as metering pumps because not only is accurate metering possible, but also a simple and flexible adjustment at a new setpoint is also possible.

The hydraulic unit transmits the movement of the piston pump to the membrane unit. The hydraulic unit has a pressure sensor which delivers an alarm signal, for example, or

interrupts the piston unit drive directly on reaching a predefinable pressure limit.

According to the present embodiment, a head piece which is characterized as "disposable" can be secured on the membrane unit and is connected to the fluid to be pumped. Thus, direct contact between this fluid and the parts of the pumping device according to the present invention is effectively prevented.

Figure 2 shows a perspective view of the pumping device according to the present invention with driving device 1 which is designed as an electric gear motor. Control lever 2 transmits the rotation of the gear motor to piston 7 by means of the self-contained cardan joint 3.

The piston rod of piston 7 has a locking element 5 mounted on a flange 4. In addition, measuring device 8, designed as a path sensor, is also mounted on flange 4.

Piston 7, designed as a precision piston, with the piston rod runs in a precision cylinder 6 with a pump cover and a tension rod.

The movements of piston 7 are transmitted to membrane unit 14 by hydraulic unit 9, which is designed as a line in the present embodiment. This membrane unit has membrane 11 bordering the first chamber 13. First chamber 13 contains vent valve 12 according to the present embodiment. If gases collect in hydraulic unit 9, they are removed from the hydraulic unit by vent valve 12, so that an incompressible transmission medium is always available between the piston unit and the membrane unit.

Pressure sensor 10, which is located in hydraulic unit 9, which is filled with hydraulic fluid, is connected to a display and/or driving device 1 by a computer, turning the device off on reaching or exceeding a definable limit value. This reliably limits the maximum pressure head in the entire system in the event of a blockade of hydraulic unit 9 or a defect in the valves or clamps of the head piece, for example.

To improve the handling of the pumping device according to the present invention, the piston unit with driving device

1 is mounted on a chassis 15.

A membrane pump head, designed as a disposable article is placed on membrane unit 14 in a manner not shown here and thus forms the second chamber, which is bordered by membrane 11 of membrane unit 14, for example.

Figure 3 shows a sectional diagram through a pumping device according to the present invention with a membrane unit 14 having a two-layer membrane 11. Membrane 11 consists of membrane layers 11' and 11'' bordering interspace 20. Both membrane layers 11', 11'' are made of a non-stretching material, e.g., reinforced by a woven fabric. Interspace 20 is filled with an incompressible medium such as oil.

The volumes of the first chamber 30 and chamber 40 arranged on the opposite side of membrane 11 remain constant regardless of the pressure gradient prevailing between the two chambers 30, 40. Consequently, this prevents the deflections that occur with known membranes due to a pressure difference across the membrane, which would thus lead to a mistaken relationship between piston position and membrane deflection.

A movement of piston 7 of the piston unit leads to displacement of the interspace 20 according to the present invention without altering its volume. A change in volume in chamber 40 is produced exclusively by the movement of piston 7 and the end piece 50 connected to it. Support 60 is provided on the side of membrane 11 facing chamber 40 to secure membrane layer 11''.

Membrane layers 11', 11'' are arranged so that they are separated by spacer 70. Spacer 70 has an orifice 72 which serves to fill interspace 20 with a suitable incompressible medium.

The pumping device according to the present invention is a pumping, balancing and metering system for medical fluids such as blood and dialysis fluids which functions reliably and is easy to handle. It can be used to particular advantage in the field of peritoneal dialysis, hemodialysis, hemofiltration and related methods. Due to the combination and connection of a piston unit with a measuring device and a membrane unit by

means of a hydraulic unit, the good properties of piston systems, extending in particular to accurate metering, are guaranteed, with the advantages of a membrane unit that permits a reliable separation of working media and delivery media, as a result of which the measuring device according to the present invention permits accurate metering and balancing.

Patent Claims

1. A pumping device for delivering and metering medical fluids in particular, comprising

a piston unit having a driving device (1) and a piston(7),

a membrane unit (14) having at least a membrane (11) and a first chamber (13) bordered by the membrane (11) and

a hydraulic unit (9) having a space to accommodate a hydraulic fluid which is connected to the piston (7) of the piston unit and to the first chamber (13) of the membrane unit (14),

characterized in that

provision is made for a control unit for controlling a predefinable metering rate and/or quantity, as well as for a measuring device (8) which can be connected to the control unit and by means of which the axial position of the piston (7) of the piston unit can be determined directly.

2. The pumping device according to Claim 1, characterized in that the piston (7) has a piston head and a piston shaft, and the measuring device (8) is arranged so that the axial position of the piston shaft can be determined.

3. The pumping device according to Claim 1 or 2, characterized in that the measuring device (8) has optical and/or electronic sensors.

4. The pumping device according to one or more of Claims 1 through 3, characterized in that a head piece can be connected detachably to the membrane unit (14) so that a second chamber is arranged on the side of the membrane opposite the first

chamber (13) is formed, with the membrane head having at least one inlet and at least one outlet.

5. The pumping device according to Claim 4, characterized in that the second chamber is directly adjacent to the membrane (11) of the membrane unit (14) when the membrane pump head is in the mounted state.

6. The pumping device according to Claim 4, characterized in that the second chamber is bordered by a membrane which is directly adjacent to the membrane (11) of the membrane unit (14) when the membrane pump head is in the mounted state.

7. The pumping device according to one of the preceding claims, characterized in that the membranes are in airless contact with one another.

8. The pumping device according to one or more of Claims 4 through 6, characterized in that the inlet and/or outlet of the membrane pump head can be blocked off.

9. The pumping device according to one or more of Claims 4 through 8, characterized in that the head piece is designed as a disposable part for one-time use.

10. The pumping device according to one or more of Claims 1 through 9, characterized in that a pressure sensor (10) is provided and is connected to the space of the hydraulic unit.

11. The pumping device according to Claim 10, characterized in that the pressure sensor (10) can be connected to the driving device (1) of the piston unit by a computer or motor controller.

12. The pumping device according to one or more of Claims 1 through 11, characterized in that the driving device (1) of the piston unit includes a linear drive.

13. The pumping device according to Claim 12, characterized in that the linear drive is formed by a rack and pinion.

14. The pumping device according to one or more of Claims 1 through 13, characterized in that the hydraulic unit has a vent valve (12).

15. The pumping device according to one or more of Claims 1 through 14, characterized in that a computing unit is provided, that is connected to the measuring device (8) and/or the control unit and is responsible for performing the metering, flow rate adjustment and thus also the balancing of the pumped media.

16. The pumping device according to Claim 15, characterized in that the computing unit is integrated into the control unit.

17. The pumping device according to one or more of Claims 1 through 16, characterized in that the piston unit is arranged on a chassis (15).

18. The pumping device according to one or more of Claims 1 through 17, characterized in that the membrane (11) of the membrane unit (14) has two membrane layers (11', 11") each made of a non-stretching material and an interspace (20) extending between the two membrane layers (11', 11") and filled with an incompressible medium so that the membrane layers (11', 11") has an outward bulge with respect to the interspace (20).

19. The pumping device according to Claim 18, characterized in that the membrane layers (11', 11") are arranged so that they are separated from one another by a spacer (70).

Abstract of the Disclosure

The present invention relates to a pumping device for delivering and metering fluids, in particular medical fluids such as dialysis fluids, with a piston unit having a driving device and a piston and with a membrane unit which has a membrane and a first chamber bordered by the membrane. The pumping device also has a hydraulic unit which has a space to accommodate a hydraulic fluid which is connected to the piston of the piston unit and to the first chamber of the membrane unit. The reliability of metering by such a pumping device is increased by providing a control unit for guaranteeing a predefinable metering rate and/or quantity and also providing a measuring device by means of which the axial position of the piston unit can be determined directly and which can be connected to the control unit.

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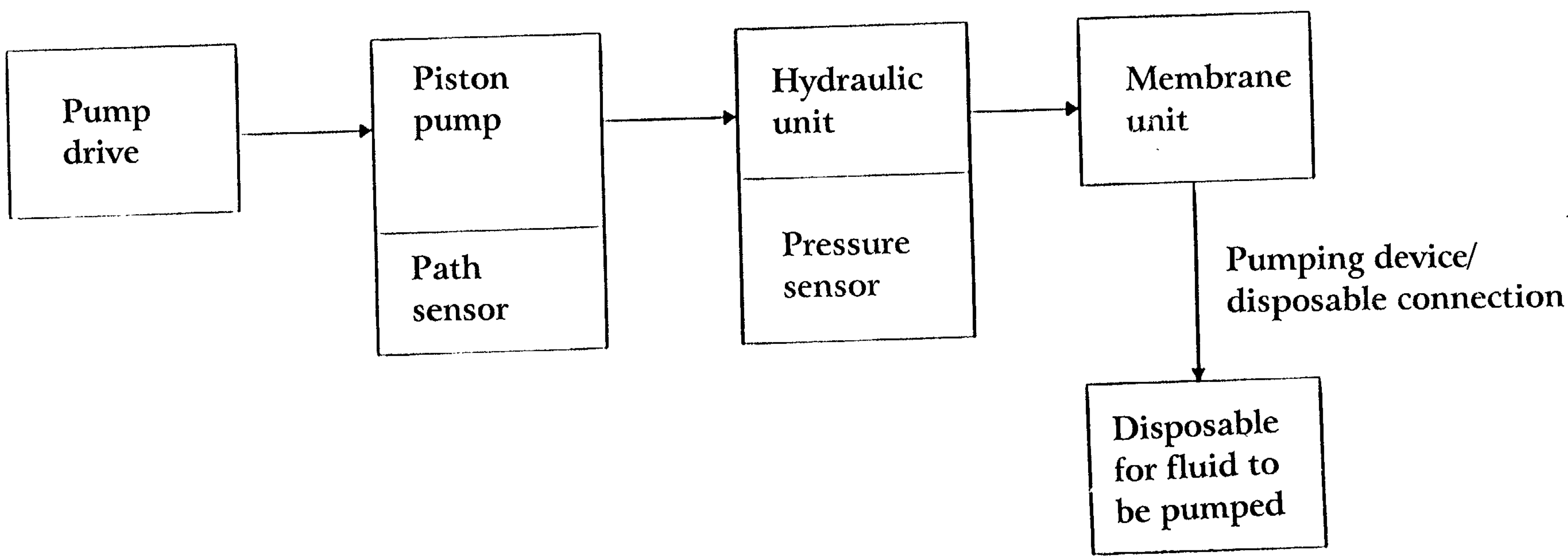
Fig. 1



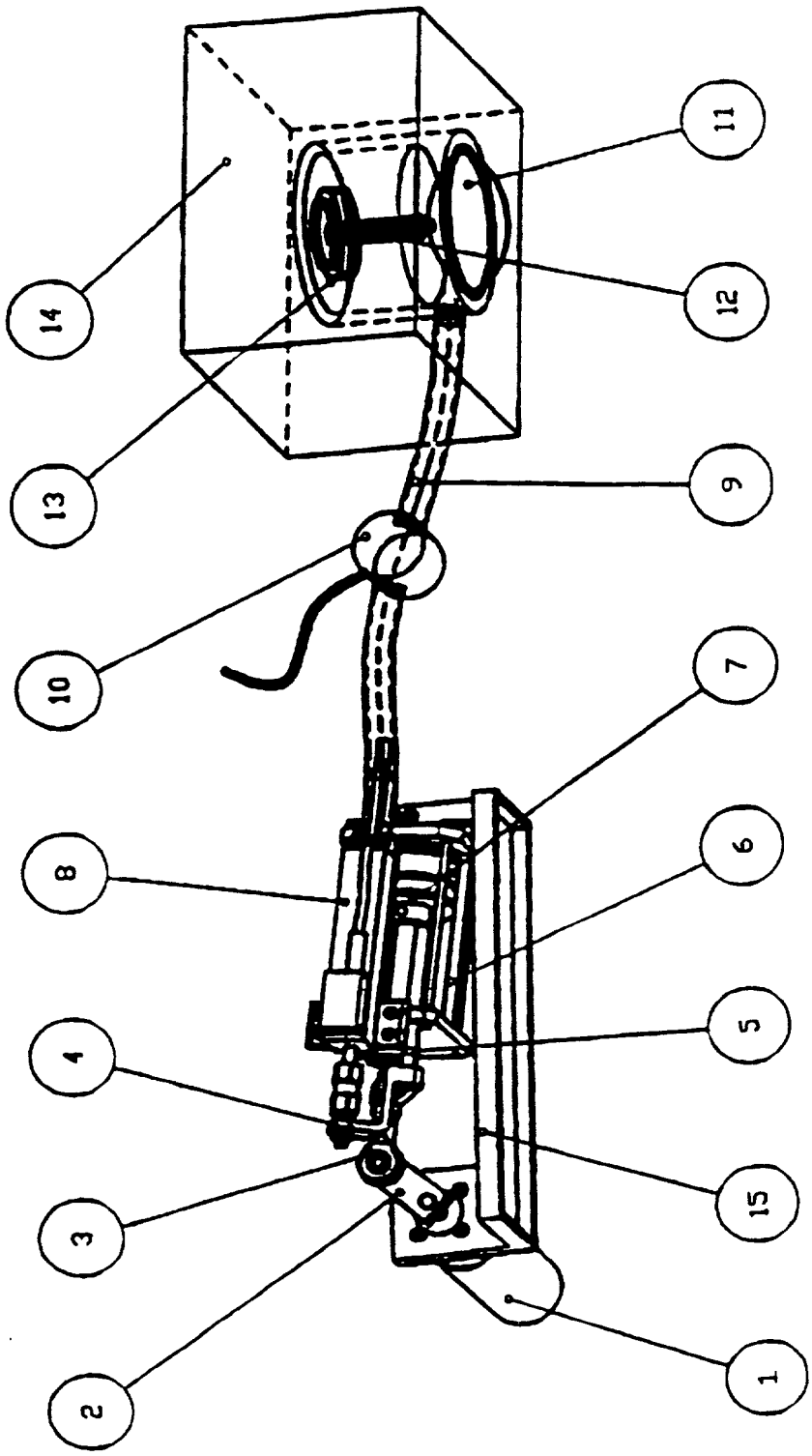


Fig. 2

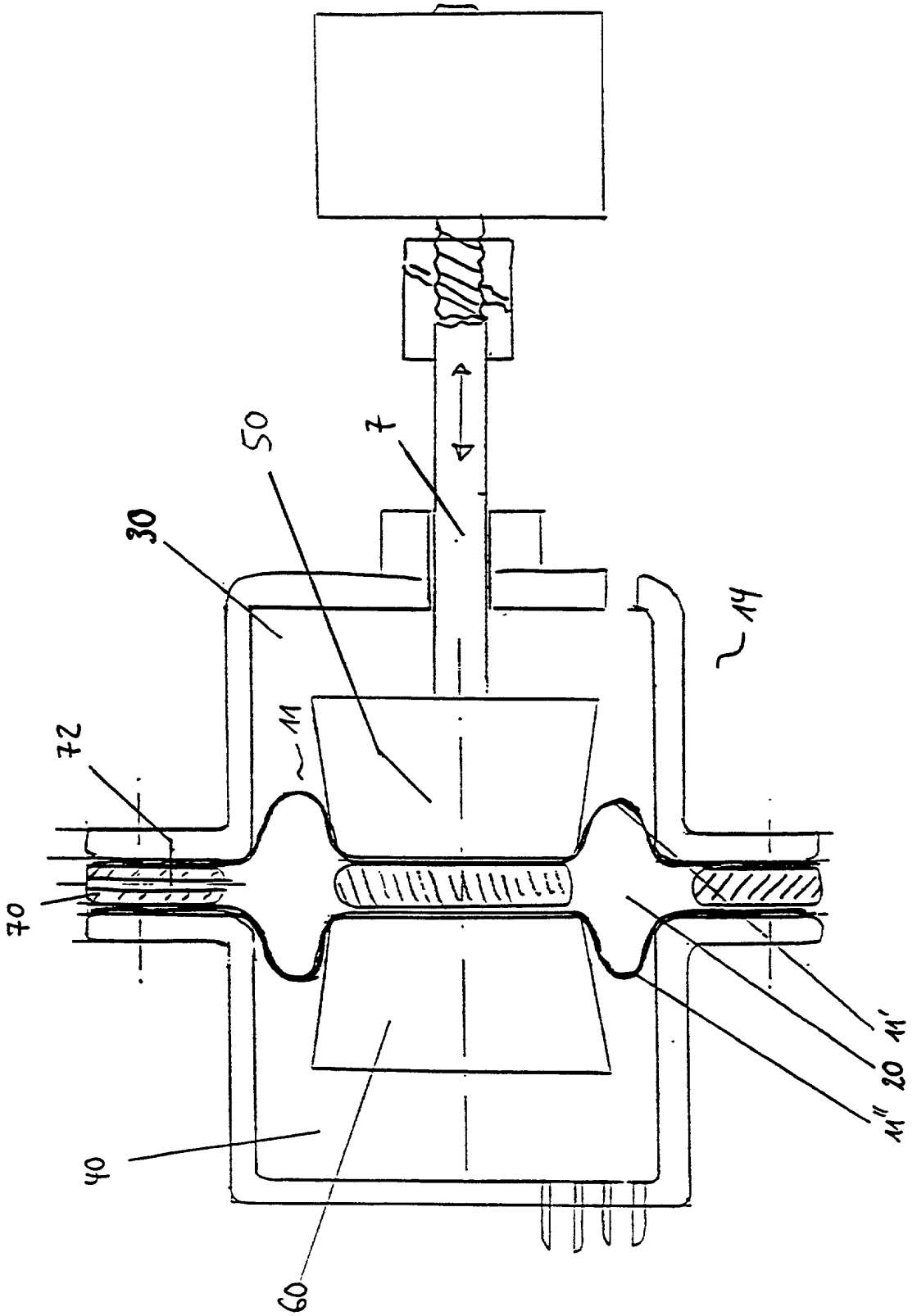


Fig. 3

Docket No.: 2565/52

DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am an original and first and joint inventor of the subject matter that is claimed and for which a patent is sought on the invention entitled **PUMPING AND METERING DEVICE,** National Phase application of PCT/EP98/01792 which was filed in the United States Patent and Trademark Office under Serial No. 09/308,914.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims.

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

PRIOR FOREIGN APPLICATION(S)

197 42 632.8	Germany	26 September 1997	Yes x No
(Number)	(Country)	(Day/month/year filed)	Priority Claimed Under 35 USC 119

EL179103687US

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I acknowledge the duty to disclose information that is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

And I hereby appoint Richard L. Mayer (Registration No. 22,490) and Thomas J. Meloro (Registration No. 33,538) my attorney with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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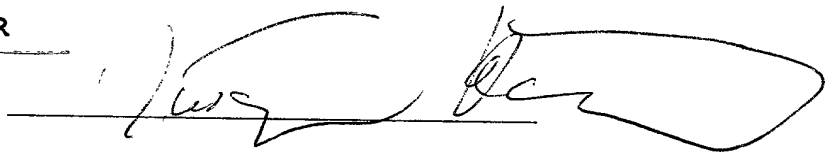
Inventor's Signature: 

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